

# PSJ3

# Exhibit 336

## **SETTLEMENT AGREEMENT**

This Settlement Agreement (“Agreement”) is entered into by and among the United States Attorney’s Office for the Middle District of Florida, acting on behalf of the United States, the Drug Enforcement Administration (“DEA”) for the Miami Division, and CVS Health and all of its subsidiaries and affiliates (collectively “CVS”) (each a “Party” and collectively the “Parties”).

### **RECITALS**

A. CVS Health is a Delaware corporation with its corporate headquarters in Woonsocket, Rhode Island. CVS Health, directly or through its retail pharmacy subsidiaries and affiliates, and through its CVS/pharmacy division, operates retail pharmacies in the State of Florida that dispense prescription drugs, including controlled substances, to retail consumers (hereafter referred to as “CVS/pharmacy retail stores”). Through its CVS/caremark division, CVS also operates mail service pharmacies that dispense prescription drugs, including controlled substances, by mail to retail consumers.

B. Each CVS/pharmacy retail store in Florida is separately registered with DEA and is assigned a unique DEA registration number that authorizes it to dispense controlled substances pursuant to the provisions of the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* (“CSA”), and its implementing regulations. The CVS/pharmacy retail stores located in Florida will be referred to collectively herein as “Florida CVS/pharmacy retail stores.”

C. Pharmacies registered with DEA as chain pharmacies are permitted to dispense prescriptions, including controlled substances, to their walk-in customers as well as by mail. For purposes of this Agreement, “Florida CVS/pharmacy retail stores” include those CVS entities,

subsidiaries, and affiliates that are located in Florida and that dispense prescriptions, including controlled substances, by mail.

D. CVS also owns and operates distribution centers in Florida that are or were registered with DEA as distributors of Schedules III-V controlled substances (collectively "Florida Distribution Centers"). Each CVS Distribution Center is separately registered with DEA and is assigned a unique DEA registration number that authorizes it to distribute controlled substances pursuant to the rules and regulations in the CSA and its implementing regulations.

E. CVS acknowledges that all of its DEA-registered CVS/pharmacy retail stores and Distribution Centers were and are required to comply with the CSA and the regulations promulgated thereunder.

F. The CSA prohibits the distribution of a controlled substance without a valid prescription. 21 U.S.C. § 842(a)(1). To be valid, a prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. 21 C.F.R. § 1306.04.

G. CVS acknowledges that it has a corresponding responsibility to dispense only those prescriptions that have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and that knowingly filling a prescription not in the usual course of professional treatment or in legitimate and authorized research subjects CVS to penalties under the CSA. 21 C.F.R. § 1306.04.

H. On October 18, 2011, DEA served Administrative Inspection Warrants on two CVS/pharmacy retail stores in Florida: (i) Store 219, which was registered with DEA as a chain pharmacy authorized to dispense controlled substances in Schedules II-V controlled substances under DEA registration number BC5289055 at 3798 Orlando Drive, Sanford, Florida; and (ii)

Store 5195, which was registered with DEA as a chain pharmacy authorized to dispense controlled substances in Schedules II-V under DEA registration number BC6988298 at 4639 West 1<sup>st</sup> Street, Sanford, Florida.

I. DEA revoked the registrations issued to CVS stores 219 and 5195 in an order published on October 12, 2012. *See* 77 Fed. Reg. 62316-01 (Oct. 12, 2012). DEA revoked the registrations of DEA stores 219 and 5195 based, among other things, on their failure to fulfill their corresponding responsibilities under 21 C.F.R. § 1306.04.

J. The United States contends that CVS failed to fulfill its corresponding responsibility under 21 C.F.R. § 1306.04 and thus is subject to civil penalties under 21 U.S.C. § 842(a)(1) and § 842(c)(1).

K. CVS acknowledges that certain CVS/pharmacy retail stores did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA and its implementing regulations.

L. At all times relevant herein, the CSA authorized the imposition of civil penalties for each of the categories of Covered Conduct as described in paragraph 2 below.

To avoid the delay, expense, inconvenience, and uncertainty of litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

**TERMS AND CONDITIONS**

1. Paragraphs A-L set forth above are fully adopted herein.
2. For purposes of this Agreement, "Covered Conduct" shall mean the following:

Florida CVS/pharmacy Retail Stores

(i) Conduct alleged in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195 and in DEA's filings in *In the Matter of Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #00219 and Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #05195*, Docket Nos. 12-37 and 12-38;

(ii) Failure of any Florida CVS/pharmacy retail store, on or before the Effective Date of this Agreement, to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04, and the dispensing, on or before the Effective Date of this Agreement, by any Florida CVS/pharmacy retail store of controlled substances pursuant to prescriptions that were invalid under 21 C.F.R. Part 1306;

(iii) Dispensing, on or before the Effective Date of this Agreement, by any Florida CVS/pharmacy retail store of controlled substances to individuals CVS knew or should have known were diverting controlled substances;

(iv) Dispensing, on or before the Effective Date of this Agreement, by any Florida CVS/pharmacy retail store of controlled substances pursuant to prescriptions issued by physicians who did not have current, valid DEA registrations;

(v) Refusal or negligent failure, on or before the Effective Date of this Agreement, by any Florida CVS/pharmacy retail store to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under subchapter I or subchapter II of the CSA and the CSA's implementing regulations, including, but not limited to, failure by any Florida CVS/pharmacy retail store to comply with

the record-keeping obligations contained in 21 C.F.R. Part 1304, and to comply with regulations regarding prescriptions contained in 21 C.F.R. Part 1306; and

(vi) Conduct by any Florida CVS/pharmacy retail store that occurred on or before the Effective Date of this Agreement and that is inconsistent with or in violation of the CSA and/or its implementing regulations.

Florida Distribution Centers

(vii) Failure, on or before the Effective Date of this Agreement, by any Florida Distribution Center to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 U.S.C. § 823(e);

(viii) Failure, on or before the Effective Date of this Agreement, by any Florida Distribution Center to timely detect and report suspicious orders of controlled substances, as required by 21 U.S.C. §§ 822 and 823 and 21 C.F.R. § 1301.74(b);

(ix) Distribution, on or before the Effective Date of this Agreement, by any Florida Distribution Center of controlled substances to a Florida CVS/pharmacy retail store that the Distribution Center knew or should have known was engaged in any of the Covered Conduct described above in paragraphs 2(i)-2(vi);

(x) Failure, on or before the Effective Date of this Agreement, by any Florida Distribution Center to make and complete accurate reports through the Automation of Reports and Consolidated Orders System (ARCOS), as required by 21 U.S.C. § 827;

(xi) Refusal or negligent failure, on or before the Effective Date of this Agreement, by any Florida Distribution Center to make, keep, or furnish any record, report,

notification, declaration, order or order form, statement, invoice, or information required under subchapter I or subchapter II of the CSA and the CSA's implementing regulations; and

(xii) Conduct by any Florida Distribution Center that occurred on or before the Effective Date of this Agreement and that is inconsistent with or in violation of the CSA and/or its implementing regulations.

3. CVS shall pay to the United States the total sum of \$22,000,000.00 (twenty-two million dollars and no cents) (the "Settlement Amount") within ten (10) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to the written instructions provided to CVS by the United States Attorney's Office for the Middle District of Florida.

4. In consideration of the undertakings of the United States contained herein, CVS fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorney's fees, costs and expenses of every kind and however denominated) that CVS has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, and agents related to the investigation, prosecution, and settlement of the Covered Conduct, provided, however, that CVS reserves and does not release any liability based on obligations created by this Agreement.

5. In consideration of the undertakings by CVS, and subject to the exceptions in Paragraph 6 below (concerning excluded claims), and conditioned upon CVS's full payment of the Settlement Amount, the United States Attorney's Office for the Middle District of Florida, acting on behalf of the United States, and the DEA for the Miami Division agree to:

(i) Release and refrain from instituting any administrative claims against CVS or any of its subsidiaries or affiliates and any of the officers, directors, employees, agents, successors, and assigns of each, arising from or related to the Covered Conduct;

(ii) Refrain from filing any action for civil penalties under 21 U.S.C. § 842 based on, arising from, or related to the Covered Conduct.

6. Notwithstanding the releases given in Paragraph 5 of this Agreement, the United States specifically reserves and does not release:

- (i) Any federal criminal liability;
- (ii) Any criminal, civil, or administrative claim arising under Title 26, United States Code (Internal Revenue Code);
- (iii) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and
- (iv) Any liability based on obligations created by this Agreement.

7. Nothing in this Agreement constitutes an Agreement by the United States Attorney's Office concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

8. This Agreement binds and is intended to benefit only the Parties. This Agreement is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein. This Agreement is specifically limited to the Office of the United States Attorney for the Middle District of Florida and the DEA for the Miami Division and cannot bind other federal, state, or local authorities and jurisdictions.

9. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

10. Each Party and signatory to this Agreement represents that he, she, or it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.



11. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Middle District of Florida. For purposes of construing this Agreement, the Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not be construed against any Party for that reason in any subsequent dispute.

12. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Each of the Parties expressly agrees and acknowledges that, in entering this Agreement, it is relying on only the statements and promises expressly set forth in this written Agreement. This Agreement cannot be amended, nor any provisions waived, except in writing and when signed by all Parties to this Agreement.

13. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties listed below.

14. This Agreement may be executed in counterparts, including by facsimile, pdf, or other electronic form of signature, each of which constitutes an original and all of which constitute one and the same Agreement.

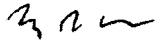
15. This Agreement inures to the benefit of and is binding on each Party and its respective successors, transferees, heirs, and assigns.

16. The Parties may disclose the existence of and information about this Agreement to the public without restriction.

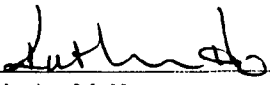
17. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). The United States agrees to notify CVS immediately when the final signatory has executed this Agreement.

[Signatures begin on next page.]

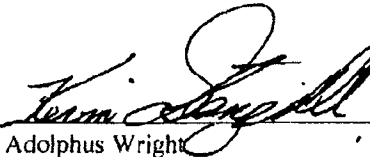
ON BEHALF OF THE UNITED STATES OF AMERICA:

  
\_\_\_\_\_  
Lacy R. Harwell, Jr.  
Chief, Civil Division  
United States Attorney's Office  
Middle District of Florida

DATE: 5-12-15

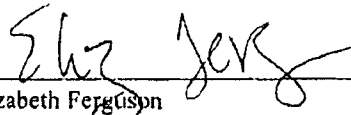
  
\_\_\_\_\_  
Katherine M. Ho  
Assistant U.S. Attorney  
United States Attorney's Office  
Middle District of Florida

DATE: 5-12-15

  
\_\_\_\_\_  
Adolphus Wright  
Acting Special Agent in Charge  
Drug Enforcement Administration,  
Miami Division

DATE: 5-11-15

ON BEHALF OF CVS PHARMACY, INC.:

  
\_\_\_\_\_  
Elizabeth Ferguson  
Senior Vice President, Assistant General Counsel  
CVS Pharmacy, Inc.

DATE: 12/18/2014